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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,081	02/20/2007	Dietmar Kubcin-Meesenburg	5047.1010	9297
7278 7590 12/24/2009 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770				
EXAMINER WOLF, MEGAN YARNALL				
ART UNIT 3738		PAPER NUMBER		
MAIL DATE 12/24/2009		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,081

Applicant(s)

KUBEIN-MEESBURG ET AL.

Examiner

Megan Wolf

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-294)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 031606

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the features wherein each of the first and second functional surfaces have orbital radii that differ from each other in a main functional plane relative to a secondary functional plane rotated by 90 degrees with respect to the main functional plane, wherein both of the first and second functional surface are non-spherical, and wherein both functional surfaces are affixable in different locking stages relative to the socket or condyle must be shown or the features canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 10 is objected to because of the following informalities: Line 3 of the claim says "a joint socket having including". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a socket having an asymmetrical functional surface, does not reasonably provide enablement for a condyle having an asymmetrical functional surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides clear detailed description of the asymmetric functional surface of the socket component shown in figures 1-3. However, there are neither drawings nor a clear description of the condyle portion having an asymmetric functional surface. An artificial joint with *each* of the functional surfaces being asymmetric as is claimed in claim 10 would be designed and function very differently from what is described and shown in the specification.

Further, the specification, while being enabling for a socket with a functional surface affixable in different positions, does not reasonably provide enablement for a

condyle with a functional surface affixable in different positions. The drawings clearly show two parts of the joint socket including a socket part and an inlay with the functional surface but only a single piece spherical condyle is shown and clearly described. It is unclear how the functional surface on the condyle is affixable in different positions given its monolithic structure and the description in the specification.

Claim 13 is also not enabled by the specification because the specification describes the first functional surface as being located on the socket rather than the condyle (see par.8) and paragraph 9 of the specification only described the functional surface on the socket as being drum-shaped, spindle-shaped, or oval. Since the claims have defined the first functional surface on the condyle, there is no support for the limitations in claim 13.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims state that the first functional surface is on the condyle and the second functional surface is on the inlay, but the specification states that the first functional surface is associated with the socket and the second functional surface is associated with the condyle (see par.8). This is unclear since features of each surface have been described one way in the specification and the opposite way in the claims. The terminology in the specification should be consistent with the claims.

Claim 11 is rejected as being indefinite because Claim 10, from which claim 11 depends, states that "each of the first and second functional surfaces have orbital radii that differ from each other in a main functional plane relative to a secondary functional plane" but claim 11 states that one of the first and second functional planes exhibits symmetrical functional planes. It is unclear how a functional surface can have orbital radii that differ in the functional planes and at the same time exhibit symmetrical functional planes. Please clarify.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10, 12-15, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubach et al. 6,485,520 in view of Shultz et al. 6,746,486. Hubach discloses an artificial joint, comprising a condyle 9 having a first functional surface 13 (fig.5), and a joint socket 3 having a socket part 35 and an inlay 43 having a second functional surface 51 (figs.11,13), the first and second functional surfaces being functionally interlinked (this is believed to mean that the bearing surfaces articulate with one another), wherein the first and second functional surface are non-spherical and oval in shape and are made of polyethylene (col.2, ll.58-60), and wherein each of the first and second functional surfaces have orbital radii that differ from each other in a main functional plane relative to a secondary functional plane rotated by 90° with respect to

the main functional plane (col.4, ll.6-14; col.5, ll.35-42). While Hubach discloses the invention substantially as claimed, Hubach does not disclose that at least one of the functional surfaces is affixable in different positions relative to the respective joint socket or condyle so as to individually adapt the artificial joint to the patient.

Shultz teaches an artificial joint, in the same field of endeavor, wherein the bearing component of the ball portion of the joint is capable of being fixed in different locking stages or positions with respect to the base for the purpose of providing the surgeon with the capability of orienting the bearing surfaces in an optimal position (fig.7; col.6, ll.38-65).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the unitary condyle of Hubach to be modular and affixable in different orientations as taught by Shultz in order to individually adapt the joint to the patient's particular anatomy.

9. Claims 10-13, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubein-Meesenburg et al. 6,312,471 in view of Pria 2003/0153982. Kubein-Meesenburg discloses the invention substantially as claimed including an artificial hip joint, comprising a condyle 2 having a first functional surface and a joint socket 1 having a second functional surface, the first and second functional surfaces being functionally interlinked, wherein at least one of the first and second functional surface is non-spherical in shape, wherein the first functional surface has orbital radii that differ from each other in a main functional plane relative to a secondary functional plane rotated by 90° with respect to the main functional plane, wherein the first

functional surface is spindle-shaped, and wherein the diameter of the first functional surface in the frontal plane of the patient is between 0.5 and 8 mm greater than a diameter of the functional surface in a sagittal plane (col.2, ll.11-13). While Kubein-Meesenburg discloses the invention substantially as claimed, Kubein-Meesenburg does not disclose that each of the functional surfaces are non-spherical or that the socket portion is in two parts including a socket part and an inlay wherein at least one of the functional surfaces is affixable in different positions relative to the respective joint socket or condyle so as to individually adapt the artificial joint to the patient.

Pria teaches a hip socket, in the same field of endeavor, wherein an inlay is affixable in different positions relative to the joint socket 12 for the purpose of being able to modify the angle of the articular insert to obtain an efficient and long-lasting functioning of the components (par.6).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hip socket of Kubein-Meesenburg to include separate socket and inlay components, as is well known in the art, and to allow for these components to be affixable in different positions as taught by Pria in order to accommodate various patient anatomy. It would have been further obvious to modify the shape of the socket of Kubein-Meesenburg so that each of the functional surfaces are asymmetric as claimed since it has been held that changes in shape are a matter of design choice, which a person of ordinary skill in the art would have found obvious as they were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kubein-Meesenburg in view of Pria as applied to claim 10 above, and further in view of Serbousek et al. 5,009,665. Kubein-Meesenburg in view of Pria discloses the invention substantially as claimed and as discussed above, however, Kubein-Meesenburg in view of Pria does not disclose that the inlay is securable by a shrinkage connection.

Serbousek teaches an acetabular cup, in the same field of endeavor, wherein the inlay is inserted into the socket while it is shrunken for the purpose of allowing it to be easily placed into the socket and be secured therein (col.3, ll.47-50).

It would have been obvious to one of ordinary skill in the art to modify the connection between the socket and inlay described by Kubein-Meesenburg in view of Pria and use a shrinkage connection as this is a well known means for securing an inlay into a socket as taught by Serbousek.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
/David H Willse/
Primary Examiner, Art Unit 3738